

**PATENT****IN THE UNITED STATES PATENT AND TRADEMARK OFFICE****In re Application of:****Tette van der Lende****Serial No.: 10/763,815****Filed: January 22, 2004****For: DIETARY MODIFICATIONS TO
IMPROVE FERTILITY****Confirmation No.: 4997****Examiner: C. Hagopian****Group Art Unit: 1615****Attorney Docket No.: 2183-6293US****NOTICE OF EXPRESS MAILING**Express Mail Mailing Label Number: EV962541592USDate of Deposit with USPS: November 19, 2007Person making Deposit: Drew Greenhalgh**DECLARATION OF DWAIN J. GUGGENBILLER**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Dr. Dwain Guggenbiller, hereby declare:

1. Since 2004, I have worked as a "Swine Technical Veterinarian" with Trouw Nutrition USA, a company affiliated and/or associated with the assignee of the referenced patent application (Nutreco Nederland BV).

2. I received my dual B.S. in Math & Chemistry and my MBA at the University of Dayton in 1985 & 1991, respectively, and my Doctor of Veterinary Medicine at The Ohio State

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University in 1993.

3. I attended an interview at the U.S. Patent & Trademark Office on October 3, 2007 concerning U.S. Patent Application Serial No. 10/763,815 ("the referenced patent application") as a representative of the owner of the referenced patent application.

4. During the interview, we discussed with the Patent Examiner and her supervisor, among other things, the composition claims of the referenced patent application (e.g., claims 1 and 10) and the difference in arginine levels between that of the referenced patent application and certain disclosures. We stated that we believed that the difference in amount of arginine is significant.

5. Herein, I explain the difference between the amounts claimed in claims 1 and 10 of the present patent application and the disclosures of U.S. Patent Application Publication 2002/0051844 A1 to Wilson et al. ("Wilson") and Don Mahan, "Digestibility of Soybean Meals Collected at Four Periods from a Soybean Processor (Cargill) in Ohio ("Mahan").

6. I am informed and believe that claim 1 of the referenced patent application currently recites:

An animal feed suitable for feeding a gestating animal and which improves the fertility of an animal fed said animal feed, which feed comprises an amount of lysine and the following amino acids in an amount relative to the amount of lysine (w/w) in the following ranges:

total methionine + cysteine:	>0.55;
threonine:	>0.60;
tryptophan:	>0.15; and
arginine:	>1.5,

wherein a daily dosage of at least 200 mg arginine per kg body of the gestating animal (kg/bw) is provided upon feeding.

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7. I am further informed and believe that claim 10 of the referenced patent application currently recites:

A premix containing arginine in a sufficient amount, upon mixing with feed, to produce an animal feed suitable for feeding a gestating animal and which improves the fertility of an animal fed said animal feed, said animal feed being enriched in arginine such that a daily dosage of at least 200 mg arginine per kg body weight of the gestating animal is provided upon feeding, which animal feed comprises an amount of lysine and the following amino acids in an amount relative to the amount of lysine (w/w) in the following ranges:

total methionine + cysteine: >0.55;
threonine: >0.60; and
tryptophan: >0.15.

8. I have read Wilson. Wilson teaches animal feed compositions and methods for increasing the reproductive performance of breeding populations of swine. Wilson's disclosure is particularly directed to a method of increasing reproductive performance of female swine by administering ω -3-fatty acids to the swine. Wilson teaches incorporating ω -3-fatty acids into "any animal feed blend known in the art" including "rapeseed meal, cottonseed meal; soybean meal, and cornmeal". Such animal feed blends can include, as "optional amino acid ingredients", "arginine, histidine, isoleucine, leucine, lysine, methionine, threonine, tryptophan, valine, tyrosine ethyl HCl, alanine, aspartic acid, sodium glutamate, glycine, proline, serine, and cysteine ethyl HCl, and analogs." (Wilson, Paragraph 0031). No further mention of arginine is believed to be made in Wilson. Wilson also teaches several methods of administration ranging from feeding the composition to the animals daily for their lifetime, to feeding the composition to an animal before and/or during pregnancy and/or during lactation. (Wilson, Paragraph 0030).

9. However, Wilson does not teach the specific amounts of amino acids recited by applicants' claims 1 and 10. Furthermore, in my opinion, Wilson does not teach or suggest modifying the amount of arginine (or the lysine to arginine ratio) in Wilson's feed to levels claimed in the referenced patent application or any effect such a modification might have with respect to improving fertility.

10. Wilson does not disclose the particularly claimed amounts of arginine (e.g., "an animal feed suitable for feeding a gestating animal, which feed comprises an amount of lysine and [arginine] in an amount relative to the amount of lysine (w/w) [of] arginine >1.5, wherein a

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daily dosage of at least 200 mg arginine per kg body of the gestating animal (kg/bw) is provided upon feeding" as recited in claim 1 of the referenced patent application

11. I have read Mahan. I am informed and believe that the Patent Examiner has stated that "Mahan teaches that soybean meal contains amino acids including arginine, lysine, methionine, threonine, tryptophan, and cysteine and provides percentage amounts for each amino acid (Table 2). Mahan also teaches that soybean meal naturally contains 0.20% calcium (Table 2)."

12. I am further informed and believe that the Patent Examiner then asserted (which statement I respectfully do not agree with) that "one of ordinary skill in the art would have been motivated to optimize the particular amounts of amino acids in the composition taught by Wilson by way of routine experimentation" presumably to the amounts set forth in claims 1 and 10.

13. I am further informed and believe (and again I respectfully disagree with the assertion) that the Patent Examiner contended that "absent unexpected results, a practitioner would reasonably expect an animal feed composition to provide the same result as suggested by Wilson; to increase the reproductive performance of breeding populations of swine. Thus in Wilson, it would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the animal feed composition."

14. First, this contention overlooks Wilson's primary teaching, *i.e.*, that omega-3 fatty acids enhance fertility. In my opinion, nothing in Wilson suggests or teaches modifying the arginine or other "optional" amino acid concentration of the feed to improve the fertility of an animal fed the animal feed.

15. Second, in regard to Mahan, Table 2 of Mahan illustrates the composition of soybean meal as including 3.56% arginine, 2.97 % lysine, 0.65% methionine, 0.76% cysteine, 1.83% threonine and 1.70% tryptophan. Relative to the amount of lysine, this gives a total amount of methionine and cysteine of less than 0.55 ($0.65 + 0.76/2.97 = 0.47$). The weight ratio between arginine and lysine is lower than 1.5 ($(3.56/2.97 = 1.20)$).

16. I do not believe that Mahan teaches or suggests the relative amounts of amino acids claimed in the referenced patent application or the benefit of the amounts of amino acids on fertility.

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17. I am further informed and believe (and again I respectfully disagree with the assertion) that the Patent Examiner believes that since soybean meal naturally contains amino acids, it would have been obvious to one of skill in the art to increase the relative amount of such amino acids to achieve the ratios of the presently claims.

18. In order to analyze this assertion, the following analysis of arginine/lysine ratio in gestating diets for sows was made by Nutreco:

Common US gestation diet:

What follows is a weight ratio calculation of arginine to lysine in the standard gestation diet for sows (as proposed by Kansas State University Nutrition Guide 2007 "Breeding Herd recommendations for Swine"):

<u>Ingredients:</u>	<u>Amount:</u>	<u>Total lysine</u>
Corn	1,626	4.1
Soybean meal (46.5 CP)	291	8.4
Vitamins/Minerals/trace elements	83	0.5
Total	2,000	13 (% amount of lysine 0.65%)

Recommended total lysine of this diet in %: 0.65% (13 grams)

No recommendation for total arginine is available. Therefore, the total content arginine was calculated as follows:

<u>Ingredients:</u>	<u>Amount:</u>	<u>Total lysine</u>	<u>Total arginine</u> <u>(calculated)</u>
Corn	1,626	4.1	6.7
Soybean meal (46.5 CP)	291	8.4	10.0
Vitamins/Minerals/trace elements	83	0.5	NA
Total	2,000	13	16.7

Thus, the arginine to lysine ratio is 16.7/13 or 1.2.

19. In order to attain a ratio of arginine to lysine of 1.5 (as claimed in, e.g., claim 1 of the patent application), extra arginine would need to be added to the standard US sow gestating diet. However, in order to achieve a ratio of arginine to lysine of at least 1.5, the total arginine in the diet would need to be 19.5, meaning that 2.8 extra synthetic arginine measurement units would need to be added to the sow's diet (or 0.14%). Such an addition would not occur,

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however, since no requirement or recommendation exists to make such an addition of arginine to a standard US sow gestating diet.

20. Since, without adding extra arginine, a ratio of arginine to lysine of above 1.2 does not occur naturally in a standard US sow gestating diet (based upon the raw material content and recommendations), and since there are no recommendations or requirements to add arginine to a gestating sow's diet, it would not have been obvious to increase the ratios to greater than 1.5.

21. Furthermore, Wilson *et al.* and Mahan do not provide any suggestion to modify or combine the references or modify them to the ratios of claims 1 and 10. Wilson is silent regarding any benefit of an increased ratio of methionine/cysteine to lysine and arginine to lysine. Wilson is silent about the relative ratios of amino acids.

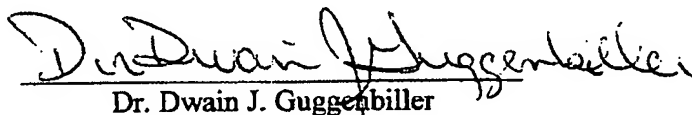
22. Further, as increasing the amount or ratio of these amino acids would significantly increase the cost of the composition, one of skill in the art would not be motivated to make such a composition without being aware of the potential benefit of the investment.

23. A person of skill in the art would also have generally believed that swine during pregnancy synthesize all the necessary arginine. According to the National Research Council (NRC), a standard handbook reference for swine breeders, excessive supplements of arginine are undesirable as they can reduce feed intake and reduce growth.

24. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patents issued thereon.

Date:

Nov 16, 2007



Dr. Dwain J. Guggenbiller